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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Birch, Stewart, Kolasch & Birch, LLP
8110 Gatehouse Rd, Suite 500 East
P.O. Box 747
Falls Church, VA 22040-0747

EXAMINER	
BOESEN, AGNIESZKA	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 05/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/667,141	SKIADOPOULOS ET AL.	
	Examiner	Art Unit	
	Agnieszka Boesen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-129,183,232,255 and 278* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-129,183,232,255 and 278* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The Examiner and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Agnieszka Boesen Group Art Unit 1648.

Applicants called on April 27, 2006 to question the Election/Restriction requirement mailed December 30, 2005. Applicants noted that in other cases the inventions are separated into products, methods of using and methods of making, In this instance the prior examiner had grouped methods of using and methods of making into the same group, but separated the polynucleotides as "partial" or "complete." Applicants' demanded that the Office issue a new Election/Restriction requirement, separating the products from the methods of making and using the compostions. Upon review and reconsideration the Election/Restriction requirement mailed mailed December 30, 2005 is herby vacated and the following new Election/Restriction is issued.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group #	Linking claims	Claims	
1	67, 70	71, 72, 129	A composition comprising a **"complete"** HPIV2 polyhexameric genome in a particle. The genome must possess N, P and L protein The composition is isolated, infectious, self-replicating. The "recombinant" requirement is read as a process (product-by-process) limitation, because it does not add to the structure of the composition, classified in class 424, subclass 211.1.
2	67, 70	72, 83, 85, 86, 129	A composition comprising a **"partial"** HPIV2 polyhexameric genome in a particle. The genome must possess N, P and L protein The composition is isolated, infectious, self-replicating. The composition is isolated, infectious, self-replicating.

			The "recombinant" requirement is read as a process (product-by-process) limitation, because it does not add to the structure of the composition, classified in class 424, subclass 211.1.
3	67, 73	74, 75, 76, 255, 278	Attenuating mutation HPIV3 JS cp45 Target at 948 and/or 1566 HPIV2 L protein, classified in class 424, subclass 211.1.
4	67, 73	74, 77, 78, 82	Attenuating mutation from RSV. Target at Phe 460 in HPIV2 L, classified in class 424, subclass 211.1.
5	67, 73	74, 79, 80	Attenuating mutation from BPIV3 Target at Ser 1724 in the HPIV2 L protein is a **substitution,** classified in class 424, subclass 211.1.
6	67, 73	74, 79, 80, 81	Attenuating mutation from BPIV3 Target at Ser 1724-1725 in the HPIV2 L protein is a **deletion,** classified in class 424, subclass 211.1.
7	67, 83	84, 85, 86, 124, 125-128	Nucleotide modification resulting in a phenotypic change. A nucleotide modification can be an insertion, deletion or substitution. Resulting in the following phenotypic change: Attenuation Temperature sensitivity Cold-adaptation Plaque size Host-range restriction Change in immunogenicity, classified in class 424, subclass 211.1
8	67, 83	83, 87, 88	Nucleotide modification (**insertion**) to encode a non-PIV molecule where the molecule is a **cytokine,** classified in class 424, subclass 211.1.
9	67, 83	87	Nucleotide modification (**insertion**) to encode a non-PIV molecule where the molecule is a **T-helper epitope,** classified in class 424, subclass 211.1.
10	67, 83	87	Nucleotide modification (**insertion**) to encode a non-PIV molecule where the molecule is a **restriction site marker.**
11	67, 83	87,	Nucleotide modification (**insertion**) to encode a non-PIV molecule where the molecule is a **protein of a microbial (bacteria or virus) pathogen,** classified in class 424, subclass 211.1
12	67, 89	90, 94, 95, 98, 99, 100, 101, 102, 103, 104	HPIV2 chimera with a heterologous gene encoding antigenic determinant. The new gene segment is added (supernumerary) in addition to the HPIV2 genes. The supernumerary heterologous gene is **HPIV1 HN,** classified in class 424, subclass 211.1.
13	67, 89	100, 104	HPIV2 chimera with a heterologous gene encoding antigenic determinant. The new gene segment is added (supernumerary)

			in addition to the HPIV2 genes. The supernumerary heterologous gene is **HPIV1 F,** classified in class 424, subclass 211.1.
14	67, 89	90, 94, 95	HPIV2 chimera with a heterologous gene encoding antigenic determinant. The new gene segment is added (supernumerary) in addition to the HPIV2 genes. The supernumerary heterologous gene is **HPIV2 F,** classified in class 424, subclass 211.1.
15	67, 89	90, 94, 95, 100, 104	HPIV2 chimera with a heterologous gene encoding antigenic determinant. The new gene segment is added (supernumerary) in addition to the HPIV2 genes. The supernumerary heterologous gene is **HPIV3 HN,** classified in class 424, subclass 211.1.
16	67, 89	90, 94, 95	HPIV2 chimera with a heterologous gene encoding antigenic determinant. The new gene segment is added (supernumerary) in addition to the HPIV2 genes. The supernumerary heterologous gene is **HPIV3 F,** classified in class 424, subclass 211.1.
17	67, 89	68, 92	HPIV2 chimera with at least one different HPIV N, P or L protein.
18	67, 89	68, 89, 120, 121, 122, 123	HPIV2 /BPIV3 chimera with at least one different BPIV3 N, P or L protein, classified in class 424, subclass 211.1.
19	67, 89	90, 94, 95	HPIV2 chimera with a heterologous gene encoding antigenic determinant with an added gene sequence. The supernumerary heterologous gene is **measles virus HA,** classified in class 424, subclass 211.1.
20	67, 89	91	HPIV2 chimera with a heterologous gene includes a regulatory element, classified in class 424, subclass 211.1 .
21	67, 89	93, 96	HPIV2 chimera with a heterologous **measles virus** pathogen sequence, classified in class 424, subclass 212.1.
22	67, 89	93, 96, 97	HPIV2 chimera with a heterologous **RSV subgroup A** pathogen sequence, classified in class 424, subclass 211.1 .
23	67, 89	93, 96, 97	HPIV2 chimera with a heterologous **RSV subgroup B** virus pathogen sequence, classified in class 424, subclass 207.1.
24	67, 89	93, 96	HPIV2 chimera with a heterologous **mumps virus** pathogen sequence, classified in class 424, subclass 211.1.
25	67, 89	93, 96	HPIV2 chimera with a heterologous **human papilloma virus** pathogen sequence, classified in class 424, subclass 211.1.
26	67, 89	93, 96	HPIV2 chimera with a heterologous **HIV type 1** virus pathogen sequence, classified in class 424, subclass 208.1 .
27	67, 89	93,96	HPIV2 chimera with a heterologous **HIV type 2** virus pathogen sequence, classified in class 424, subclass 208.1.
28	67, 89	93, 96	HPIV2 chimera with a heterologous **HSV** virus pathogen

			sequence, classified in class 424, subclass 211.1.
29	67, 89	93, 96	HPIV2 chimera with a heterologous **cytomegalovirus** pathogen sequence, classified in class 424, subclass 211.1.
30	67, 89	93, 96	HPIV2 chimera with a heterologous **rabies** virus pathogen sequence, classified in class 424, subclass 211.1 .
31	67, 89	93, 96	HPIV2 chimera with a heterologous **human metapneumovirus** pathogen sequence, classified in class 424, subclass 211.1.
32	67, 89	93, 96	HPIV2 chimera with a heterologous **Epstein Barr** virus pathogen sequence, classified in class 424, subclass 211.1.
33	67, 89	93, 96	HPIV2 chimera with a heterologous **filovirus** pathogen sequence, classified in class 424, subclass 211.1.
34	67, 89	93, 96	HPIV2 chimera with a heterologous **bunyavirus** pathogen sequence, classified in class 424, subclass 211.1.
35	67, 89	93, 96	HPIV2 chimera with a heterologous **flavivirus** pathogen sequence, classified in class 424, subclass 211.1.
36	67, 89	93, 96	HPIV2 chimera with a heterologous **alphavirus** pathogen sequence, classified in class 424, subclass 211.1 .
37	67, 89	93, 96	HPIV2 chimera with a heterologous **influenza virus** pathogen sequence, classified in class 424, subclass 211.1 .
38	67, 89	105, 106, 107	HPIV2 chimera with an attenuating mutation HPIV3 JS cp45 Target at 948 and/or 1566 HPIV2 L protein, classified in class 424, subclass 211.1
39	67, 89	105, 108, 109	HPIV2 chimera with an attenuating mutation from RSV with a **substitution** at corresponding target position Phe 460 in HPIV2 L protein, classified in class 424, subclass 211.1.
40	67, 89	105, 111, 123	HPIV2 chimera with an additional attenuating mutation from BPIV3. Here the target at Ser 1724 in the HPIV2 L protein is a **substitution,** classified in class 424, subclass 211.1.
41	67, 89	105, 111, 112	HPIV2 chimera with an additional attenuating mutation from BPIV3. Here the target at Ser 1724 in the HPIV2 L protein is a **deletion,** classified in class 424, subclass 211.1.
42	67, 89	105, 114, 115,	HPIV2 / HPIV1 chimera that comprises an additional attenuating mutation, classified in class 424, subclass 211.1.
43	67, 89	105, 113, 116, 117, 118	HPIV2 chimera that comprises an additional attenuating mutation (insertion deletion, substitution) resulting in any one of the following phenotypic changes: Attenuation Temperature sensitivity Cold-adaptation Plaque size Host-range restriction Change in immunogenicity Here the attenuation is a partial or complete **deletion** of HPIV2

			V, classified in class 424, subclass 211.1.
44	67, 89	116, 119	HPIV2 chimera that comprises an additional attenuating mutation (insertion) resulting in a phenotypic change where the inserted non-PIV molecule is a **cytokine,** classified in class 424, subclass 211.1.
45	67, 89	116, 119	HPIV2 chimera that comprises an additional attenuating mutation (insertion) resulting in a phenotypic change where the inserted non-PIV molecule is a **T-helper epitope,** classified in class 424, subclass 211.1.
46	67, 89	116, 119	HPIV2 chimera that comprises an additional attenuating mutation (insertion) resulting in a phenotypic change where the inserted non-PIV molecule is a **restriction site marker,** classified in class 424, subclass 211.1.
47	67, 89	116, 119	HPIV2 chimera that comprises an attenuating mutation (insertion) resulting in a phenotypic change where the inserted non-PIV molecule is a **protein of a microbial pathogen (bacteria or virus),** classified in class 424, subclass 277.1.
48	1	2, 3, 4, 5,	A method of making a composition comprising a **"complete"** HPIV2 polyhexameric genome in a particle. The genome must possess N, P and L protein The composition is isolated, infectious, self-replicating. The "recombinant" requirement is read as a process (product-by-process) limitation, because it does not add to the structure of the composition, classified in class 435, subclass 5.
49	1	2, 3, 4,	A method of making a composition comprising a **"partial"** HPIV2 polyhexameric genome in a particle. The genome must possess N, P and L protein The composition is isolated, infectious, self-replicating. The composition is isolated, infectious, self-replicating. The "recombinant" requirement is read as a process (product-by-process) limitation, because it does not add to the structure of the composition, classified in class 435, subclass 5.
50	1, 9	11, 12, 13, 14	A method of making a composition comprising an attenuating mutation HPIV3 JS cp45 Target at 948 and/or 1566 HPIV2 L protein, classified in class 435, subclass 5.
51	1, 9	15, 16	A method of making a composition comprising an attenuating mutation from RSV. Target at Phe 460 in HPIV2 L, classified in class 435, subclass 5.
52	1, 9	17, 18	A method of making a composition comprising an attenuating mutation from BPIV3 Target at Ser 1724 in the HPIV2 L protein is a **substitution,** classified in class 435, subclass 5.

53	1, 9	17, 18, 19	A method of making a composition comprising an attenuating mutation from BPIV3 Target at Ser 1724-1725 in the HPIV2 L protein is a **deletion,** classified in class 435, subclass 5.
54	1, 21	8, 20, 21, 22, 23, 24, 25	A method of making a composition comprising a nucleotide modification resulting in a phenotypic change. A nucleotide modification can be an insertion, deletion or substitution. Resulting in the following phenotypic change: Attenuation Temperature sensitivity Cold-adaptation Plaque size Host-range restriction Change in immunogenicity, classified in class 435, subclass 5.
55	1, 21, 27	25, 26,	A method of making a composition comprising a nucleotide modification (**insertion**) to encode a non-PIV molecule where the molecule is a **cytokine,** classified in class 435, subclass 5.
56	1, 21, 27	25, 28	A method of making a composition comprising a nucleotide modification (**insertion**) to encode a non-PIV molecule where the molecule is a **T-helper epitope,** classified in class 435, subclass 5.
57	1, 21, 27	25, 28	A method of making a composition comprising a nucleotide modification (**insertion**) to encode a non-PIV molecule where the molecule is a **restriction site marker,** classified in class 435, subclass 5.
58	1, 21, 27	25, 28	A method of making a composition comprising a nucleotide modification (**insertion**) to encode a non-PIV molecule where the molecule is a **protein of a microbial (bacteria or virus) pathogen,** classified in class 435, subclass 5.
59	1, 27,	32, 33, 35-40, 42	A method of making a composition comprising HPIV2 chimera with a heterologous gene encoding antigenic determinant. The new gene segment is added (supernumerary) in addition to the HPIV2 genes. The supernumerary heterologous gene is **HPIV1 HN,** classified in class 435, subclass 5.
60	1, 27	32, 33, 37, 39	A method of making a composition comprising HPIV2 chimera with a heterologous gene encoding antigenic determinant. The new gene segment is added (supernumerary) in addition to the HPIV2 genes. The supernumerary heterologous gene is **HPIV1 F,** classified in class 435, subclass 5.
61	1, 27	32, 33, 37, 39	A method of making a composition comprising HPIV2 chimera with a heterologous gene encoding antigenic

			determinant. The new gene segment is added (supernumerary) in addition to the HPIV2 genes. The supernumerary heterologous gene is **HPIV2 F,** classified in class 435, subclass 5.
62	1, 27	32, 33, 37, 39, 42	A method of making a composition comprising HPIV2 chimera with a heterologous gene encoding antigenic determinant. The new gene segment is added (supernumerary) in addition to the HPIV2 genes. The supernumerary heterologous gene is **HPIV3 HN,** classified in class 435, subclass 5.
63	1, 27	32, 33, 37, 39, 42	A method of making a composition comprising HPIV2 chimera with a heterologous gene encoding antigenic determinant. The new gene segment is added (supernumerary) in addition to the HPIV2 genes. The supernumerary heterologous gene is **HPIV3 F,** classified in class 435, subclass 5.
64	1, 27	6, 30	A method of making a composition comprising HPIV2 chimera with at least one different HPIV N, P or L protein.
65	1, 27	6, 58-61	A method of making a composition comprising HPIV2/BPIV3 chimera with at least one different BPIV3 N, P or L protein.
66	1, 27	31, 32, 33	A method of making a composition comprising HPIV2 chimera with a heterologous gene encoding antigenic determinant with an added gene sequence. The supernumerary heterologous gene is **measles virus HA,** classified in class 435, subclass 5.
67	1, 27	29	A method of making a composition comprising HPIV2 chimera with a heterologous gene includes a regulatory element, classified in class 435, subclass 5.
68	1, 27	31, 34	A method of making a composition comprising HPIV2 chimera with a heterologous **measles virus** pathogen sequence, classified in class 435, subclass 5.
69	1, 27	31, 34	A method of making a composition comprising HPIV2 chimera with a heterologous **RSV subgroup A** pathogen sequence.
70	1, 27	31, 34	A method of making a composition comprising HPIV2 chimera with a heterologous **RSV subgroup B** virus pathogen sequence, classified in class 435, subclass 5.
71	1, 27	31, 34	A method of making a composition comprising HPIV2 chimera with a heterologous **mumps virus** pathogen sequence, classified in class 435, subclass 5.
72	1, 27	31, 34	A method of making a composition comprising HPIV2 chimera with a heterologous **human papilloma virus** pathogen sequence, classified in class 435, subclass 5.
73	1, 27	31, 34	A method of making a composition comprising HPIV2

			chimera with a heterologous **HIV type 1** virus pathogen sequence, classified in class 435, subclass 5.
74	1, 27	31, 34	A method of making a composition comprising HPIV2 chimera with a heterologous **HIV type 2** virus pathogen sequence, classified in class 435, subclass 5.
75	1, 27	31, 34	A of making a composition comprising HPIV2 chimera with a heterologous **HSV** virus pathogen sequence, classified in class 435, subclass 5.
76	1, 27	31, 34	A method of making a composition comprising HPIV2 chimera with a heterologous **cytomegalovirus** pathogen sequence, classified in class 435, subclass 5.
77	1, 27	31, 34	A method of making a composition comprising HPIV2 chimera with a heterologous **rabies** virus pathogen sequence, classified in class 435, subclass 5.
78	1, 27	31, 34	A method of making a composition comprising HPIV2 chimera with a heterologous **human metapneumovirus** pathogen sequence, classified in class 435, subclass 5.
79	1, 27	31, 34	A method of making a composition comprising HPIV2 chimera with a heterologous **Epstein Barr** virus pathogen sequence, classified in class 435, subclass 5.
80	1, 27	31, 34	A method of making a composition comprising HPIV2 chimera with a heterologous **filovirus** pathogen sequence, classified in class 435, subclass 5.
81	1, 27	31, 34	A method of making a composition comprising HPIV2 chimera with a heterologous **bunyavirus** pathogen sequence, classified in class 435, subclass 5.
82	1, 27	31, 34	A method of making a composition comprising HPIV2 chimera with a heterologous **flavivirus** pathogen sequence, classified in class 435, subclass 5.
83	1, 27	31, 34	A method of making a composition comprising HPIV2 chimera with a heterologous **alphavirus** pathogen sequence, classified in class 435, subclass 5.
84	1, 27	31, 34	A method of making a composition comprising HPIV2 chimera with a heterologous **influenza virus** pathogen sequence, classified in class 435, subclass 5.
85	1, 27	43,44, 45	A method of making a composition comprising HPIV2 chimera with an attenuating mutation HPIV3 JS cp45 Target at 948 and/or 1566 HPIV2 L protein, classified in class 435, subclass 5.
86	1, 27	43, 46, 47	A method of making a composition comprising HPIV2 chimera with an attenuating mutation from RSV with a **substitution** at corresponding target position Phe 460 in HPIV2 L protein, classified in class 435, subclass 5.
87	1, 27	43, 48, 49	A method of making a composition comprising HPIV2

			HPIV2 L protein, classified in class 435, subclass 5.
87	1, 27	43, 48, 49	A method of making a composition comprising HPIV2 chimera with an additional attenuating mutation from BPIV3. Here the target at Ser 1724 in the HPIV2 L protein is a **substitution,** classified in class 435, subclass 5.
88	1, 27	43, 48, 48, 50	A method of making a composition comprising A of making a composition comprising HPIV2 chimera with an additional attenuating mutation from BPIV3. Here the target at Ser 1724 in the HPIV2 L protein is a **deletion,** classified in class 435, subclass 5.
89	1, 27,	43, 51, 52, 53-56, 62-66	A method of making a composition comprising HPIV2 chimera that comprises an additional attenuating mutation (insertion deletion, substitution) resulting in any one of the following phenotypic changes: Attenuation Temperature sensitivity Cold-adaptation Plaque size Host-range restriction Change in immunogenicity Here the attenuation is a partial or complete **deletion** of HPIV2 V, classified in class 435, subclass 5.
90		183, 232	A method of vaccinating a subject to elicit an immune response against PIV, classified in class 435, subclass 5.

The inventions are distinct, each from the other because of the following reasons:

Inventions (1)-(47) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, represent structurally different viral particles having different polynucleotides. Therefore, where structural identity is required, such as for hybridization or expression using the polynucleotide, the different sequences have different effects. The different sequences also will encode different epitopes, so that the protein they encode have different effects.

Groups 1-47 are compositions and are distinct from groups 48-90 which are drawn to methods. Groups 1-47 are compositions and each is distinct from the other because they contain different materials. Though there may be overlap for these groups, the search for one group (structure) will not be coextensive with that of the other group.

Groups 48-89 are drawn to methods and each is distinct from the other because they utilize different starting materials, therefore the outcomes are not be expected to be the same. Groups 48-89 are drawn to a method of producing HPIV2 viral particles having different mutations, growth characteristics or epitopes. Though there may be overlap between these methods in question for groups 48-89, each utilizes different materials and therefore the outcome is expected to be different. Group 90 is a method for immunizing a subject. The method of group 90 uses different steps from the other methods of group 48-89, thereby setting it apart. It differs from the other methods by utilizing different starting materials and techniques, the outcome would therefore not be expected to be the same.

Inventions 48-54 and 1-7 are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case viruses can be mutated or attenuated by the prolonged incubation of the virus in cell culture or by chemical mutagenesis.

Inventions 1-47 and 90 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case a subject can be immunized using isolated and inactivated viral compositions. In the alternative the virus particles can be used to produce proteins that can them be used in detection assays as well as immunization procedures.

Claims 67 link(s) inventions of groups 1-47. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 67. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Claims 67, 89 link(s) inventions of groups 3-47. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 67 and 89. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Claims 67, 70 link(s) inventions of groups 1-2. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 67 and 70. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Claims 67, 73 link(s) inventions of groups 3-6. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 67 and 73. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Claims 67, 83 link(s) inventions of groups 7-10. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 67 and 83. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Claim 1 link(s) inventions of groups 48-89. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 1. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Claims 1 and 27 link(s) inventions of groups 55-89. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 1 and 27. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the

linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Claims 1, 9 link(s) inventions of groups 50-53. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 1 and 9. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Claims 1, 21 link(s) inventions of groups 54-58. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 1 and 21. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim(s) including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the literature and sequence searches required for each of the Groups are not required for another of the Groups, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnieszka Boesen whose telephone number is 571-272-8035. The examiner can normally be reached on 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AB
Agnieszka Boesen, Ph.D.
Examiner
May 4, 2006

ULRIKE WINKLER, PH.D.
PRIMARY EXAMINER 5/4/06